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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,913	07/30/2003	Michael Garabedian	GARABEDIAN=2A	8615

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EXAMINER	
GAMETT, DANIEL C	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 02/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/629,913	GARABEDIAN ET AL.	
	Examiner	Art Unit	
	Daniel C Gamett	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *4-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07/30/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of claims 1-3 in the reply filed on 12/09/2004 is acknowledged. The traversal is on the ground(s) that the elected claims and those of Group VII (claims 9-11) are directed to antibody molecules specific for a structurally similar antigen, glucocorticoid receptors phosphorylated at a different serine residue, and that the searches for both groups would be coextensive. Applicant therefore requested withdrawal of the requirement for restriction insofar as Groups I and VII are concerned. This is found persuasive because the search for Group I has proven to be substantially coextensive with Group VII. The requirement for restriction between Group I, claims 1-3, and Group VII, claims 9-11, is hereby withdrawn.

2. Claims 4-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/09/2004.

Objection to the Specification

3. The disclosure is objected to because of the following informalities: The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

4. The disclosure is objected to because of the following informalities: The peptides used to raise antibodies are inconsistently described. The sequence listing shows SEQ ID NOs 1 and 2 as each consisting of 10 amino acids whereas they are described as having 14 amino acids in section [0042] and in figure 1. The sequence listing indicates that residue 8 of SEQ ID NO:3 is phosphorylated. This is apparently a typographical error as residue 8 is a leucine and not the phosphoserine at position 9 shown in section [0042].

Appropriate correction is required.

Claim Rejections 35 U.S.C. 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-3 and 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 and Claim 9 are drawn to antibodies specific for glucocorticoid receptor phosphorylated residue Ser 211 or Ser 226 (claim 1) or Ser 203 (claim 9). These claims are vague because they fail to recite a reference sequence upon which the numbering of residues is based. They even fail to recite the species of glucocorticoid receptor in question, even though the specification indicates that applicants intend to claim antibodies specific for the human glucocorticoid receptor. Nobody knows how many species of glucocorticoid receptor have serines at the designated positions.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> a. The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-3 and 9-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are directed to antibody molecules specific for glucocorticoid receptors with a specific phosphorylation pattern, wherein the source or overall structure of the glucocorticoid receptor is not recited in the claims. Thus the claims encompass a virtually infinite number of antibodies that bind a virtually infinite number of receptors. The specification discloses polyclonal antibodies that bind human glucocorticoid receptors comprising SEQ ID NOs: 1,2, or 3. These species are not representative of the large genus encompassed by the claims. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

9. With the exception of SEQ ID NOs: 1,2, or 3, the skilled artisan cannot envision the detailed chemical structure of the immunogen to be used to raise the encompassed antibodies, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of

isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

10. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

11. Therefore, only antibodies specific for human glucocorticoid receptors comprising the amino acid sequences set forth in SEQ ID NOs: 1,2, or 3., but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

12. Claims 1-3 and 9-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention. Because of the inconsistent manner in which the immunogens are disclosed, the skilled artisan would need to perform undue experimentation to make the claimed antibodies. Furthermore, should the specification be amended to provide a clear description of the immunogens, the instant claims would be enabled only for antibodies raised using the disclosed immunogens and not for the broad class of antibodies encompassed by the claims. The claims are directed to antibody molecules specific for glucocorticoid receptors with a specific phosphorylation pattern, wherein the source or overall structure of the glucocorticoid receptor is not recited in the claims. Thus, according to the claims, the receptors need not be of human origin and the immunogens need not comprise SEQ ID NOs:

1,2, or 3. Due to the large quantity of experimentation necessary to make and characterize antibodies against a vast array of different glucocorticoid receptors, the lack of direction/guidance presented in the specification regarding antibodies directed to other species of glucocorticoid receptor, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which established the unpredictability of outcome when different peptides are used a immunogens, and the breadth of the claims which fail to recite functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Rejection under 35 U.S.C. 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

14. Claims 1-3 and 9-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Wang et al., J. Biol. Chem., Vol. 277, Issue 29, 26573-26580, July 19, 2002, originally published In Press as doi:10.1074/jbc.M110530200 on May 8, 2002. Wang et al., teach the antibodies specific for human glucocorticoid receptor phosphorylated at Ser 211 (as in claim 1) and Ser 203 (as in claim 9). The authorship of the Wang et al. paper includes an individual not listed as an inventor on the instant application, and this indicates the claimed invention was known or used by others before Aug 13, 2002, the priority date of the instant application.

Conclusion

15. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett, Ph.D., whose telephone number is 571 272 1853. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

DCG
Art Unit 1647
16 February 2005

ELIZABETH KEMMERER
PRIMARY EXAMINER